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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/762,302	02/08/2001	Rango Dietrich	P66333USO	4778

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	11

DATE MAILED: 09/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/762,302	DIETRICH ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Amendment C, received by the Office April 29, 2003.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 21-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,260,069 to Chen in view of WO 97/02020 to Dietrich *et al.* .

Chen teaches a unit dosage form for delivery drugs into the body, wherein a plurality of populations of pellets is provided within a unit dosage form such as a capsule (abstract). The plurality of pellets or particles are completely enclosed within said capsule, each population of pellets constructed to release a drug into said environment of use, whereby all of said pellets are release from said capsule substantially simultaneously, and exposed to the environment when the

capsule disintegrates (c 6, claim 1). Each pellet contains a core including a drug and a swelling agent, which can be crospovidone (c 6, claim 1 and c 7, claims 6). Additionally, each pellet is coated with a coating membrane containing (a) a water insoluble, permeable polymer and one or both of (b) a diffusion controlling agent, and (c) a dissolution controlling agent (column 3, lines 10-16). The water insoluble film former can be a cellulose derivative, an acrylic resin, a copolymer of acrylic acid and methacrylic acid esters with quaternary ammonium groups, or copolymers of acrylic acid and methacrylic acid esters (c 7, claim 7). The water soluble film former can be a phthalate, HPMC, shellac and others (c 7, claim 9). Chen does not teach the use of a specific drug in his formulation, instead he teaches that the formulation can be used with a variety of active agents (column 3, lines 31-32).

Dietrich *et al.* disclose an oral pharmaceutical composition of pantoprazole in pellet or tablet form, wherein the drug is at least partly in slow release form, and is administered in combination with an antimicrobial active (abstract). Furthermore, Dietrich *et al.* teach that the slow release form has a core, at least one intermediate layer controlled release of the active agent and an outer enteric layer which is soluble in the small intestine. Additionally, Dietrich *et al.* teach that the intermediate coating can be a methacruylate polymer (Eudragits). Dietrich *et al.* also teach that traditional excipient can be included, such as cross linked polyvinylpyrrolidone as a disintegrant (p 8, last line).

It is the position of the examiner that one of ordinary skill in the art would have been motivated to combined the teachings of Chen and Dietrich *et al.* . Chen discloses a new type of dosage form, comprising a capsule containing pellets with varying rates of release. Chen does not specify any particular active agent or class of active agents to be used with his invention.

Dietrich *et al.* is relied upon for the teaching that benzimadazoles, including pantoprazole, are known in formulations with varying release. Furthermore, Dietrich *et al.* is relied upon to show that varying rates of release is beneficial for an active agent, such as a benzimadazole, which is desired to have effects over a long period of time. One skilled in the art would have been motivated to use an active, such as that disclosed by Dietrich *et al.* , in a new type of formulation, such as that disclosed by Chen. The expected result would be a successful pharmaceutical formulation, with varying release rates, so that the active agent may have the desired effect over a longer period of time. Taking a known type of dosage form, such as the system disclosed by Chen, and using a known active agent in the formulation, is not patentable, absent a showing of criticality or unexpected results. For these reasons, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
9/17/2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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